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10/534,567	05/12/2005	Jean-Francois Biegun	CAC.P0046	6534

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EXAMINER

WOODALL, NICHOLAS W

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.



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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 10/534,567
Filing Date: May 12, 2005
Appellant(s): BIEGUN ET AL.

Edward G. Greive
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed November 15th, 2010 appealing from the Office action mailed June 9th, 2010.

(1) Real Party in Interest

The examiner has no comment on the statement, or lack of statement, identifying by name the real party in interest in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The following is a list of claims that are rejected and pending in the application:

Claims 12, 13, 15-21, and 25 are rejected and pending.

(4) Status of Amendments After Final

The examiner has no comment on the appellant's statement of the status of amendments after final rejection contained in the brief.

(5) Summary of Claimed Subject Matter

The examiner has no comment on the summary of claimed subject matter contained in the brief.

(6) Grounds of Rejection to be Reviewed on Appeal

The examiner has no comment on the appellant's statement of the grounds of rejection to be reviewed on appeal. Every ground of rejection set forth in the Office action from which the appeal is taken (as modified by any advisory actions) is being maintained by the examiner except for the grounds of rejection (if any) listed under the

subheading "WITHDRAWN REJECTIONS." New grounds of rejection (if any) are provided under the subheading "NEW GROUNDS OF REJECTION."

(7) Claims Appendix

The examiner has no comment on the copy of the appealed claims contained in the Appendix to the appellant's brief.

(8) Evidence Relied Upon

5,910106	Morgan	6-1999
5454815	Geisser	10-1995
1396934	Judd	11-1921

(9) Grounds of Rejection

1. Claims 12, 13, and 20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 20 appears to imply a limitation directed to the exposing of the plastic material to radiation hardens the material, i.e. ...so that after this exposition, said plastic material is hard enough to remove the part of the bone from the bone when said rasp is used.... A limitation directed to the exposure of a plastic material to radiation to harden the plastic material is

not supported by the disclosure as originally filed. The specification filed on May 12th, 2005 does not disclose exposing a plastic material to radiation to strengthen the plastic material. The only reference to exposing the plastic material to radiation is on page 2 lines 29-30 and page 3 lines 1-6, which discloses the exposing the plastic material to radiation to sterilize the device, wherein trying to sterilize the device a second time, either by radiation or by an autoclave, would destroy the device. Furthermore, the amended claims filed on June 26th, 2006 do not disclose a limitation directed to the plastic material being exposed to radiation to strengthen the plastic material. Therefore, the disclosure as originally filed does not support the limitation and the examiner is treating the limitation as new matter.

2. Claim 15, 16, and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Geisser (U.S. Patent 5,454,815).

Geisser discloses a device made from a plastic material including a carbon fiber reinforcing insert completely embedded within the plastic material, such as polyethylenes (column 3 lines 7-12), that come into contact with a bone to rasp the bone. The plastic material is hard enough to rasp the bone of the hip or knee and wears out after a single use (column 1 lines 29-35; column 1 lines 40-67), wherein the plastic is inherently capable deteriorating when put into an autoclave set to at least 137 degrees Celsius. The examiner would like to note that Geisser discloses the device can be made from polyethethylenes, which is a specific material listed by the appellant in the specification for the body of the rasp (page 4 lines 24-25). Therefore, the device inherently has the capability of deteriorating at 137 degrees Celsius, since they are

made from the same materials and the appellant provide the melting temperature range for the materials. Also, the examiner would like to note that Geisser discloses that all rasps dull during use and that any dullness is a considerable disadvantage suggesting that all rasps wear out after a single use causing significant problems such as longer operation time and overheating (see column 1 lines 29-35). Geisser then discloses his invention directed to a single use plastic rasp that will be discarded after use to alleviate the need for sterilization and cleaning (see column 1 lines 61-64). Therefore, the examiner believes Geisser clearly discloses a device that wears out after a single use and is then discarded.

3. Claims 17-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Geisser (U.S. Patent 5,454,815) in view of Judd (U.S. Patent 1,396,934).

Geisser discloses the invention as claimed except for the insert being made from a metal. Geisser discloses a device made from a plastic material including a carbon fiber reinforcing insert completely embedded within the plastic material in order to reinforce the plastic material. Judd teaches a device made from a plastic material including a metallic reinforcing insert completely embedded within the plastic material in order to reinforce the plastic material. Because both Geisser and Judd teach devices comprising reinforcing inserts for plastic materials, it would have been obvious to one having ordinary skill in the art at the time the invention was made to substitute one reinforcing insert with the other in order to achieve the predictable result of reinforcing the plastic material.

The device of Geisser and modified by Judd disclose the invention as claimed except for the insert being made from a shape memory material. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the device of Geisser as modified by Judd wherein the insert is made from a shape memory material, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 USPQ 416.

4. Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over Geisser (U.S. Patent 5,454,815) in view of Morgan (U.S. Patent 5,910,106).

Geisser discloses the invention as claimed except for the plastic material being exposed to radiation. Morgan teaches exposing a plastic medical instrument with gamma radiation in order to sterilize the device (column 6 lines 10-12). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the device of Geisser wherein the plastic material is exposed to gamma radiation in view of Morgan in order to sterilize the device.

5. Claims 12, 13, and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Geisser (U.S. Patent 5,454,815) in view of Morgan (U.S. Patent 5,910,106).

Geisser discloses a method comprising the steps of providing a body made from a plastic material including a carbon fiber reinforcing insert completely embedded within the plastic material, such as polyamides (column 3 lines 7-12), that come into contact with a bone to rasp the bone, wherein the plastic is hard enough to rasp the bone and

wears out after a single use (column 1 lines 29-35; column 1 lines 40-67), wherein the plastic is inherently capable deteriorating when put into an autoclave set to at least 137 degrees Celsius. Geisser fails to disclose the method further comprising the step of exposing the device to gamma or beta radiation. Morgan teaches a method comprising the step of exposing a device to gamma radiation in order to sterilize the device (column 6 lines 10-12). It would have been obvious to one having ordinary skill in the art at the time the invention was made to perform the method of Geisser further comprising the step of exposing the device to gamma radiation in view of Morgan in order to sterilize the device.

(10) Response to Argument

6. The appellant's argument that claims 12, 13, and 20 are supported by the originally filed disclosure is not persuasive. Claim 20 recites ...exposing said plastic material to beta or gamma rays, so that after this exposition, said plastic material is hard enough to remove the part of the bone from the bone when said rasp is used.... The appellant argues that the claim language is not directed to the radiation making the plastic harder, but that the language is directed to a physical characteristic of the plastic material that must be satisfied after exposure to the radiation. The examiner does not agree with this interpretation of the claim. The claim language is clearly directed to the plastic being exposed to radiation, so that after the exposure the plastic is hard enough to rasp bone. Furthermore, the appellant's argument filed on November 30th, 2006 (see page 7 lines 21-30) directed to the Morgan reference recites that the Morgan reference

does not teach radiating the plastic material to make the material hard enough to remove bone. The appellant further recites that new claim 20 specify the method of exposing the plastic material to radiation such that the plastic material is hard enough to remove bone when used.

7. The appellant's argument that the Geisser reference does not disclose a bone rasp hard enough to remove bone is not persuasive. First, the Geisser reference is directed to a plastic bone rasp. Second, the appellant relies upon the declarations filed by the appellant showing a plastic rasp made from polycarbonate plastic is too soft prior to radiation treatment making, which shows that the Geisser reference is not capable of removing bone. However, the appellant does not provide data for all the different materials disclosed by Geisser, such as polyamides, and therefore has not shown the Geisser reference as being incapable of removing bone. Lastly, the Geisser reference discloses plastic materials, such as polyamides, which the disclosure of the current invention discloses as having all the required physical characteristics and as being perfectly suited for bone rasps (see page 3 lines 7-20).

8. The appellant's argument that there is no motivation to combine the teachings of Morgan with the disclosure of Geisser is not persuasive. The appellant argues that Geisser teaches a one time use rasp that avoids the need for cleaning and sterilization, and therefore teaches away from sterilizing the device as taught by Morgan. However, column 1 lines 64-66 of the Geisser reference explicitly states that device is sterilized after manufacturing and prior to packaging. Therefore, the Geisser reference does not teach away from sterilizing the device prior to use on a patient.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

Nicholas Woodall
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/Cris L. Rodriguez/
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